Biosciences, Biotechnology Research Asia Vol. **4**(2), 821-822 (2007)

Spectrophotometric method for the determination of Atorvastatin calcium in pharmaceutical formulations

S. VIJAYA SARADHI[1]*, G. DEVALA RAO[2], P.S.K. BHARGAV[3], B. RAMANA[3], K.R. MANIKANTA[3] and G. PAVAN KUMAR[3]

[1]Dept.of.Biotechnology, Koneru Lakshmaiah College of Engineering, Vaddeswaram - 522 502 (India).
[2]K.V.S.R. Siddhartha College of Pharmaceutical Sciences, (India).
[3]P.B.Siddhartha College of Arts & Science, Vijayawada - 520 010 (India).

(Received: April 25, 2007; Accepted: August 21, 2007)

ABSTRACT

A simple, sensitive and reproducible spectrophotometric method is developed for the determination of Atorvastatin calcium in bulk and in pharmaceutical formulations. This Method is based on the reaction of Atorvastatin calcium with Fe (III) of ferric chloride and Conc. hydrochloric acid to produce a yellow orange colored chromogen (λ_{max} at 400 nm). Results of analysis were validated statistically and by recovery studies. This method is successfully employed for the determination of Atorvastatin calcium in various pharmaceutical preparations.

Key words : Atorvastatin calcium, Visible Spectrophotometric determination, Beer's Law.

Atorvastatin calcium[1, 2] (ATS) is an antihyperlipoproteinemic drug widely used in the management of obesity. It is useful in lowering blood LDL cholesterol by inhibiting HMG CoA reductase enzyme. It is chemically (BR, SR)-2-(4- fluoro phenyl)- β,δ - di hydroxy-5-(-methyl ethyl)-3-phenyl -4-[(phenyl amine) carbonyl]-1H-pyrrole-1-heptanoic acid. A thorough survey of the literature revealed only very few methods reported for the determination of ATS.They include HPLC[3] and extractive spectrophotometry[4] .The analytically useful function groups of ATS have not been fully exploited. The authors have made some attempts in this direction and succeeded in developing this spectrophotometric method for the assay. Method is based on reaction of ATS with Fe^{+3} and conc. HCL yellow orange chromogen (λ_{max} at 400nm)

Instrumentation

Spectral and absorbance measurements are made with Systronics UV - Visible Double beam spectrophotometer model 2201.

Reagents

All the chemicals used were of analytical grade. All the solutions were freshly prepared with double distilled water. Freshly prepared solutions were always used. Aqueous solutions of Ferric chloride (1%w/v) and hydrochloric acid (0.5 N) are prepared.

Standard and Sample solution of Atorvastatin calcium

About 100 mg of Atorvastatin calcium (bulk or formulation) was accurately weighed and dissolved in 100 ml of water in a volumetric flask to make a solution of 1 mg/ml standard solution and further dilutions are made with the same solvent.

Assay Procedure Method A

Aliquots 0.5-2.5 ml of standard Atorvastatin calcium (100μg/mL) was transferred to a series of 5 ml graduated tubes. The volume was made up to 2.5 mL with distilled water. To each tube 2 mL of ferric chloride solution and 0.5 mL of conc. hydrochloric acid were added and kept aside for three minutes, and the absorbance of the yellow orange colored chromogen was at 400 nm against the reagent blank. The amount of Atorvastatin calcium was computed form the calibration curve.

The proposed method was based on reaction of Atorvastatin with ferric chloride and conc. HCl based on the formation of yellow orange colored

chromogen. This reaction is a typical example of schiff's base formation. The optical characteristics such as absorption maxima, Beer's Law limits, molar absorptivity and Sandell's sensitivity for this method were presented in Table -1. The regression analysis using the method of least squares was made for the slope (a), intercept (b) and correlation coefficient (r) obtained from different concentrations was summarized in Table 1. The precision and accuracy were found by analyzing six replicate samples containing known amounts of the drug and the results are summarized in Table 1.

The accuracy of this method was ascertained by comparing the results obtained with the proposed and reference method in the case of formulations and is presented in Table 2. As an additional check on the accuracy of this method, adding known amounts of pure drug to pre-analyzed formulations. Performed recovery experiment and percent recovery values obtained are listed in Table 2. Recovery experiment indicated the absence of interferences from the commonly encountered pharmaceutical additives and excipients.

Thus the proposed method is simple and sensitive with reasonable precision and accuracy. This can be used for the routine determination of Atorvastatin calcium quality control analysis.

Table 1: Optical characteristics, precision and accuracy of the proposed method

Parameters	Method
λ_{max} (nm)	400
Beer's law limit (µg/ml)	5 - 25
Sandell's Sensitivity	0.06648
(µg/cm^2/0.001 abs. unit)	1.73776
Molar absorptivity	
(Litre.mole^{-1}.cm^{-1})	0.9951
Correlation coefficient (r)	
Regression Equation (Y)*	
Slope (a)	1.253
Intercept (b)	0.00142
% RSD**	0.4957%
% Range of errors	
(95% confidence limits)	
0.05 significance level	± 0.4144
0.01 significance level	± 0.61235

* Y= a + bx, where'Y'is the absorbance and x is the concentration of Atorvastatin calcium in ìg/ml
** For six replicates.

Table 2: Estimation of atorvastatin calcium in pharmaceutical formulations

Formulations	Labeled amount mg/tablet	% Recovery byproposed method
Tablet - 1	5mg	99.51
Tablet - 1	5mg	99.61
Tablet - 1	5mg	99.72
Tablet -1	5mg	100.5

ACKNOWLEDGEMENTS

The authors are grateful to K.L.C.E. Vaddeswaram and Siddhartha Academy, Vijayawada for their continuous support and encouragement and for providing the necessary facilities.

REFERENCES

1. The Merck index, 13th edition, Merck research laboratories, Merck and co, INC – white house station, NJ, P.149 (2001).
2. Satoskar, R.S., Bhandarkar, S.D, and Nirmala, N.R., "pharmacology and phamacotherapeutics", 19th edition, popular prakashan, 581 (2005).
3. Erturk, S., Sevinc aktas, E., Ersoy, L. and Ficicioglu, S., *Journal of Pharmaceutical and Biomedical Analysis*, **33**(5): 1017(2003).
4. *Analytical letters*, **36**(12): 2669(2003).
5. Syamsundar, B., Devala Rao, G.and Das, V.G., *Acta Ciencia Indica*, **30**(4): 263(2004).
6. Reddy, M.N., Reddy, D.S., Sankar, D.G.and Sridhar, The eastern pharmacist. 119 (1998).
7. Sastry, C.S.P., Naidu.P.Y and Murthy, SSN. Eastern pharmacist. 133 (1997).
8. Syamsundar, B., Gupta, M.E. and Devala Rao, G., *Acta Ciencia Indica.* **30**(3): 249 (2004).
9. Chowdary, K.P.R. and Devala Rao, G., *Indian Drugs,* **34**(5): 283(1997).